



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MEMORANDUM

DATE: April 21, 2020

SUBJECT: Thymol – Mutagenesis and Inhalation Toxicity Studies Waiver

PC Code: 080402	DP Barcode: 455685
Decision No.: 558521	Registration No.: N/A
Petition No.: N/A	Regulatory Action: Study Waiver
Risk Assess Type: DRA	Case No.: 3143
TXR No.: N/A	CAS No.: 89-83-8
MRID No.: 50886301, 50886302, 50886303	40 CFR: N/A

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Agency Conclusion: The Agency has waived the requirement for the 90-day inhalation toxicity and mutagenicity studies (*in vitro* mammalian chromosomal aberration test, unscheduled DNA synthesis in mammalian cells in culture test, *in vitro* sister chromatid exchange assay, and *in vivo* sister chromatid exchange assay) for Thymol.

EXECUTIVE SUMMARY:

On September 16, 2019, the Agency published the Registration Review Draft Risk Assessment for Thymol (U.S. EPA, 2019). The Agency concluded that based on low oral toxicity and low exposures from pesticidal uses relative to other pesticidal or non-pesticidal uses, the Agency is not conducting a quantitative risk assessment for thymol. In addition, the Agency concluded that no further mutagenicity assessment is required as studies were equivocal and the last study reviewed showed thymol was not mutagenic in the micronucleus assay and the mouse lymphoma assay with and without S2 activation (Maisanaba *et al.*, 2015). Thus, the Agency has recommended the mutagenesis and inhalation studies be waived.

WAIVER CITATIONS:

1. MRID 50886301 – Submitted waiver for the *in vitro* mammalian chromosomal aberration test.
2. MRID 50886302 – Submitted waiver for unscheduled DNA synthesis in mammalian cells in culture test, *in vitro* sister chromatid exchange assay, and *in vivo* sister chromatid exchange assay
3. MRID 50886303 – Submitted waiver for the 90-day inhalation toxicity study.

REFERENCES:

U.S. EPA (2019) Registration Review Draft Risk Assessment for Thymol. Docket No.: EPA-HQ-OPP-2010-0002. DP452852.

Maisanaba, S., Prieto, A.I., Puerto, M., Gutiérrez-Praena, D., Demir, E., Marcos, R., and Cameán, A.M. (2015) *In vitro* genotoxicity testing of carvacrol and thymol using the micronucleus and mouse lymphoma assays. *Mutation Research* 784-785: 37-44.